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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,827	07/22/2003	Erich Handler	RDID 03044 US	9065
23690	7590	06/27/2006	EXAMINER	
Roche Diagnostics Corporation, Inc. 9115 Hague Road PO Box 50457 Indianapolis, IN 46250-0457			GORDON, BRIAN R	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/624,827

Applicant(s)

HANDLER ET AL.

Examiner

Brian R. Gordon

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7-22-03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings filed on July 22, 2003 are acceptable subject to correction of the informalities indicated on the attached "Notice of Draftsperson's Patent Drawing Review," PTO-948.

### ***Specification***

2. The spacing of the lines of the specification is such as to make reading difficult. New application papers with lines 1½ or double spaced on good quality paper are required.

### ***Claim Interpretations***

3. Claim 10 states the device "can be heated or cooled". An operator or user can do whatever he wishes with device. As such it's optional and not a structural limitation. Claims 25 and 26 are directed to intended use. What one intends to use the pipette for is not relevant to the structure a pipette remains a pipette regardless what its use. As to claim 26, there is no antecedent basis for "said air flow". Furthermore "air flow" and intended use of air flow are not a structural limitations of the device, but are directed to intended use.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-14, 17, 19, 21-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Shumate, US 2003/0082632.

Shumate discloses an apparatuses and methods for conducting processes, such as biological and biochemical processes (involving compounds such as oligomers; see for example paragraphs 68 and 71), that provide a fluid environment in which such processes can be conducted in the presence of a substantially laminar flow of the fluid through the environment (abstract).

With reference to FIGS. 1 and 2, the flow cell 110 includes at least one inlet or access port 125 and at least one outlet or exit port 130. The ports 125, 130 are both in fluid communication with the flow chamber 115. The access port 125 forms an inlet conduit that can be used to flow fluid into the flow chamber 115. The exit port 130 forms an outlet conduit that can be used to flow fluid out of the flow chamber 115. In this regard, the access port 125 and exit port 130 define an entryway and exitway, respectively, of a flow path that fluid follows as the fluid flows into, through and out of the flow chamber 115 along a flow path, which is shown using arrows 135 in FIG. 1 and arrows 220 in FIG. 2. The ports can be resealable by using materials such as, but not limited to, rubber, silicone, silicone-rubber, or other elastomeric material suitable for forming a resealable port. The access port 125 can serve as an input port for the introduction of fluids, such as by a pipette 310 (as shown in FIG. 3) by syringe, by

cannula, by a pumping device, or by any method known in the art for transfer of fluids (paragraph 91).

The test compounds may be provided, e.g., injected, free in solution, or may be attached to a carrier, or a solid support, e.g. (microarray device)

The walls of a flow chamber (such as the walls 120, 123, 210, 215) may be formed by a sealing film made from a transparent material such as, but not limited to, polyolefin (paragraph 114).

The sealing film can be such that it is transparent for optical imaging, for microscopy, and for fluorescence readers. The sealing film can be of sufficient optical transparency and clarity to permit observation of an analyte, such as cells (paragraph 115; optical interface).

The access port 125 for the flow chamber 115 can be sealed or can be open in a fashion that is compatible with the appropriate labware such as, but not limited to, pipette tips, syringe needles, pumps, and cannula, that can be used to introduce fluid into the flow chamber (paragraph 116).

The contents of the flow chamber are incubated for an appropriate time period as determined by one of skill in the art (0148).

The flow cells 110 provided herein can be made from polymers, plastic, or any such suitable material, and are of a size such that at least one cross sectional dimension is greater than about 500  $\mu\text{m}$  In one embodiment, a flow chamber has a circular cross-sectional dimension of about 6.7 mm in diameter, and a rectangular

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 14-16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shumate, US 2003/0082632.

Shumate does not specify the manufacturing materials of glass ceramic or aluminum oxide.

Shumate does disclose the flow cells 110 provided herein can be made from polymers, plastic, **or any such suitable material**, and are of a size such that at least one cross sectional dimension is greater than about 500  $\mu\text{m}$ . In one embodiment, a flow chamber has a circular cross-sectional dimension of about 6.7 mm in diameter, and a rectangular cross-sectional dimension of 2 mm on each side. The flow chamber could also be oval-shaped, with the dimensions being about 1-4 mm long and 1-3 mm wide (0117).

As such it would have been obvious to one of ordinary skill in the art at the time of the invention to recognize various manufacturing materials may be employed including glass ceramic and aluminum oxide.

As to claim 20, Shumate discloses the flow chamber 115 can be sealed or can be open in a fashion that is compatible with the appropriate labware such as, but not limited to, pipette tips, syringe needles, pumps, and cannula, that can be used to introduce fluid into the flow chamber.

While a membrane pump is not specified it would have been obvious to one of ordinary skill in the art at the time of the invention to recognize such a conventional pump may be employed within the device.

10. Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shumate as given above in view of Wardlaw US 2002/0055178.

Shumate discloses the use of various imaging technologies but does not disclose the particulars of the optical scanning means as claimed.

Wardlaw discloses an apparatus and method for analyzing a sample of biologic fluid quiescently residing within a chamber.

The preferred embodiment of the field illuminator 40 varies depending upon the principle used to produce the image. Referring to FIG. 4, a first embodiment of the field illuminator 40 utilizes fluorescence to produce an image. The first embodiment includes a flash tube type light source 44, optics 46, and a light filtering means 48, the latter of two which include a first lens 56, a light source excitation filter 58 ("LSE" filter), a light diverting prism 60, a reference detector 62, an objective lens 52, a sample emission filter 66 ("SE" filter), a second lens 67, and a focusing mechanism 50.



It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Shumate to include the imaging and detecting system of Wardlaw to analyze the biological compounds within the chamber.

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Polizzotto; Leonard et al.; Chow; Calvin Y. H.; Wright, David W. et al.; Hooper, Herbert H. et al.; McNeely, Michael et al.; Bedingham; William et al.; Jones; Aaron C. et al.; Jerome; Jeremy et al.; Petersen; Kurt E. et al.; Bedingham; William et al.; Harms; Michael R. et al.; Ullman; Edwin F. et al.; Cottingham; Hugh V. et al.; Reichler; Allen S. et al.; Oberhardt; Bruce J.; Deoms; James H. et al.; Long; Ernest W.; Siddons; George et al.; Chang, Ronald et al.; Grossman, Robert et al.; Loeffler; Herbert H. et al.; Chang; Ronald et al.; Winkler; James L. et al.; Seher; Jens-Peter et al.; and Hirota; Toshikazu et al. disclose various cartridges and testing devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to be "E. J. M.", with a long horizontal flourish extending to the right.

brg